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Strictly Oral Presentation

Meeting at NIH Regarding Patients Injected With Plutonium

1. Dr. Ronald W. Lamont-Havers, Deputy Director, National Institute of Arthritis, Metabolism and Digestive Diseases, and Dr. Donald T. Chalkley, Chief of Institutional Relations Branch, Division of Research Grants, both of NIH, Mr. Marcus A. Rowden, OGC, and Drs. Liverman and Marks, DBER, met in Dr. Lamont-Havers' office at NIH on 3/7/74 from 8:30 until 9:45 am. The meeting was held to obtain advice from the NIH attendees regarding appropriate handling of the matter of the patients injected with plutonium from 1945-1947. After reading a briefing paper, the group discussed the following matters that pertain principally to current and future action.

2. There was a consensus that any future studies on these patients will require the approval of an Institutional Review (Human Use) Committee in each participating organization. The potential importance of the results of the studies would be expected to be a factor in the recommendations of the committees.

3. Disclosure to the patients or relatives of the patients was considered essential unless an attending physician considers such disclosure to be seriously detrimental to a patient's health.

4. The possibility that this matter may receive publicity after the meeting of the International Congress of Radiation Research in July makes it imperative that these and any other measures recommended here be taken at the earliest possible date.

5. A wrap-up of the matter, including consideration of whether and how survivors of deceased subjects should be notified, was advised. Dr. Lamont-Havers recommended that National Academy of Sciences (NAS) be approached to provide a committee review of the matter after disclosure and institutional review (2 and 3 above) are completed. NAS was suggested because of its standing as a prestigious, neutral and disinterested body. An NAS committee report, which could be appropriately published, would be likely to have wide acceptance, and the existence of the report might limit the duration of any controversy that may arise.

Dr. Chalkley proposed a medicolegal Clinical Pathologic Conference (CPC) in a medical institution as a means of opening the matter to free discussion. The conference would include medical specialists and, probably, students. Publication of the transcript of the conference would then serve the same function as publication of the committee report discussed in the last paragraph.

AEC attendees favored the alternative of an NAS committee as suggested by Dr. Lamont-Havers in view of the need for sober, careful consideration rather than the spontaneous discussion of the matter that occurs during a CPC.

If the NAS route is chosen, Dr. Lamont-Havers recommended an early contact with NAS to alert them to the problem and the need for a formal review. Such early action would document AEC's responsible approach to the problem through its willingness to have the NAS review its actions.

6. The attendees agreed that publication of scientific reports of ongoing studies not be limited but that all efforts be made to safeguard the anonymity of the patients. The NIH personnel warned that the lack of

publicity to date despite the past publication of results in monographs and reports would not prevent later notoriety if the matter is considered newsworthy by the press.

7. Such considerations as the propriety of the injections under the conditions that existed in 1945 and the various legal liabilities were not discussed. The discussion was largely confined to a consideration of the appropriate course of action to be taken by the AEC in the light of the principles and procedures recommended by DHEW for studies of human subjects.

8. As a result of the above meeting, the following course of action is projected. The Director, DBER, should:

   a. Hold an early meeting with the Director of ANL, Director of ANL Radiological and Environmental Research Division, and ANL General Counsel to inform them of the AEC position of requiring thorough compliance in this matter with ethical considerations as prescribed by the DHEW guidelines, to include early disclosure to the patients with due regard for the physician-patient relationship as discussed above and immediate referral of the issue of continuation of the studies to the ANL Institutional Review Committee;

   b. Institute immediate contact with high-level U. of Rochester personnel to inform them of the attitudes and actions of AEC as detailed here. An advisory role is appropriate at Rochester since the personnel involved there are not from our Rochester contractor organization;

   c. Institute immediate contact with the President, NAS, to brief him and request him to initiate steps leading to a rapid, thorough review and report on the matter by NAS.

9. In addition to these external actions, the Director, DBER would:

   a. Conduct a thorough investigation to obtain as complete information as possible about the early and late events and the names of participants;

   b. Conduct an in-house review, including a legal review, by OGC of questions concerning any liabilities that might be incurred by the Government;

   c. Closely monitor the progress of the above activities:

   d. Give due consideration to the advisability, timing and manner of public disclosure of this matter.